








USE OF RTV SILICONE COMPOSITIONS FOR WOUND DRESSING

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Abstract of WO0074738

In one embodiment, the present invention relates to a method of treating a wound, involving applying to the wound a room temperature vulcanizing silicone composition comprising a crosslinkable polymer, a crosslinking agent, and a catalyst; permitting the room temperature vulcanizing silicon composition to cure thereby forming a membrane having a thickness from about 0.1 mm to about 5 mm; and removing the membrane from the wound after at least about 1 day.

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(54) Title: **USE OF RTV SILICONE COMPOSITIONS FOR WOUND DRESSING**

(57) Abstract: In one embodiment, the present invention relates to a method of treating a wound, involving applying to the wound a room temperature vulcanizing silicone composition comprising a crosslinkable polymer, a crosslinking agent, and a catalyst; permitting the room temperature vulcanizing silicon composition to cure thereby forming a membrane having a thickness from about 0.1 mm to about 5 mm; and removing the membrane from the wound after at least about 1 day.

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TITLE: USE OF RTV SILICONE COMPOSITIONS FOR WOUND DRESSING

Technical Field

The present invention relates to treating skin wounds, especially those resulting from surgery, by applying a specifically defined silicone composition over the wounds.

Background of the Invention

5 Skin wounds, whether caused by injury or surgery, raise several concerns. One concern is scarring. Scarring in many instances results in a diminished sense of touch, weak regions in the skin (where scars join unwounded skin), and obvious cosmetic problems. Scarring is presently associated with injury and surgical wounds. It is therefore desirable to minimize scarring.

10 Another concern is infection or contamination. This is because an exposed wound is an ideal breeding ground for harmful bacteria. Even with conventional dressings, infections are fairly common. It is therefore desirable to minimize infections.

15 Yet another concern is providing an effective wound dressing. Wound dressings must adhere to a wound, yet possess releaseability characteristics enabling a non-damaging removal from the wound. Wound dressings must also stretch/flex to accommodate skin or bodily movement. Depending upon where the dressing is located, it is sometimes desirable to decrease the conspicuousness, for example facial dressings. Wound dressings are characterized by frequent changing which is not only time consuming, but also leads to the undesirable production of medical waste. It is therefore desirable to provide improved wound dressings.

20 Laser surgery is associated with using a small, powerful beam of light to make a small burn or opening. Typically, the laser is used to remove unwanted, damaged, or diseased cells (layers of skin) without harming the surrounding healthy cells. Laser surgery is frequently used to treat sun-damaged skin, wrinkles, and scars including acne scars, among other uses. An undesirable consequence of laser surgery is post-operative redness.

25 Laser surgery healing involves skin regeneration, similar to healing conventional burn wounds. This is different from traditional surgery using a

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scalpel. Traditional surgery healing involves skin repair. Thus, there are unique demands associated with treating a laser surgery wound compared with traditional surgery wounds. Since laser surgery is a developing medical procedure, improvements in treating laser surgery wounds are necessary.

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Summary of the Invention

The present invention relates to treating skin wounds, especially those resulting from laser surgery, by applying a specifically defined silicone composition over the wounds. The present invention provides improved wound dressings in that the silicone based dressings do not need to be changed every day, as conventional dressings require. The silicone based dressings adequately adhere to a wound, yet possess releaseability enabling the non-damaging removal of the dressing from the wound. The silicone based dressings further minimize scarring and minimize potential infections. Another benefit associated with the silicone based dressings used in accordance with the present invention is the reduction of post-operative redness (reduction of the hue intensity of the redness as well as the duration of any redness).

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In one embodiment, the present invention relates to a method of treating a wound, involving applying to the wound a room temperature vulcanizing silicone composition comprising a crosslinkable polymer, a crosslinking agent, and a catalyst; permitting the room temperature vulcanizing silicon composition to cure thereby forming a membrane having a thickness from about 0.1 mm to about 5 mm; and removing the membrane from the wound after at least about 1 day.

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In another embodiment, the present invention relates to a method of treating a laser surgery wound, involving combining a first composition comprising a first crosslinkable polymer and a crosslinking agent with a second composition comprising a second crosslinkable polymer and a platinum catalyst to form a room temperature vulcanizing silicon composition comprising the first and second crosslinkable polymers, the crosslinking agent, and the platinum catalyst; applying to the laser surgery wound the room temperature vulcanizing silicon composition; permitting the room temperature vulcanizing silicon composition to cure thereby forming a substantially transparent membrane having a thickness from about 0.25

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mm to about 3 mm; and removing the substantially transparent membrane from the laser surgery wound after at least about 2 days.

In yet another embodiment, the present invention relates to a method of treating a laser surgery wound, involving combining a first composition comprising a first crosslinkable polymer and a crosslinking agent with a second composition comprising a second crosslinkable polymer and a platinum catalyst to form a room temperature vulcanizing silicon composition comprising the first and second crosslinkable polymers, the crosslinking agent, and the platinum catalyst; applying to the laser surgery wound the room temperature vulcanizing silicon composition; permitting the room temperature vulcanizing silicon composition to cure thereby forming a substantially transparent membrane having a thickness from about 0.25 mm to about 3 mm; and removing the substantially transparent membrane from the laser surgery wound after at least about 4 days.

Description of the Preferred Embodiments

The present invention generally provides treatments for surgical wounds. In one embodiment, the present invention provides a method of facilitating healing of surgical wounds. In another embodiment, the present invention provides a method of preventing infection of surgical wounds. In yet another embodiment, the present invention provides a method of minimizing scarring due to surgical procedures. In a specific embodiment, the present invention provides a method of facilitating healing of surgical wounds caused by laser surgery.

The present invention involves using a room temperature vulcanizing (RTV) silicone composition to cover surgical wounds, especially wounds from laser surgery, to facilitate at least one of wound healing, infection prevention, and scarring minimization. The RTV silicone composition is preferably an addition cured RTV silicone composition, although a condensation cured RTV silicone composition may be employed. In one embodiment, the RTV silicone composition is a two-part RTV silicone composition. In another embodiment, the RTV silicone composition is an RTV silicone elastomer.

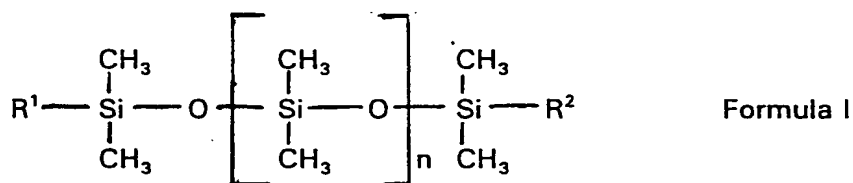
The RTV silicone composition contains at least three components; namely; a crosslinkable polysiloxane, a crosslinking agent, and a catalyst. In many embodiments, the RTV silicone composition further contains at least one optional

additives including fillers and medicaments. In embodiments where the RTV silicone composition is a two-part RTV silicone composition, one part contains the crosslinking agent while a second part contains the catalyst. Typically both parts contain the crosslinkable polysiloxane, and one or both parts may contain at least one optional additive.

The RTV silicone composition contains a crosslinkable polysiloxane. Crosslinkable polysiloxanes are known as curable silicone prepolymers; that is, a polysiloxane having one or more functional groups, such as vinyl groups, which enable the prepolymer to be polymerized or cured to a state of higher molecular weight. Suitable silicone prepolymers are known in the art and are described, for example, in "Silicones", *Kirk-Othmer Encyclopedia of Chemical Technology*, 3rd Ed., 20, 922-962 (1982), which is incorporated by reference in this regard.

Crosslinkable polysiloxanes are made by an equilibrium process from siloxanes or other polysiloxanes and typically range in viscosity from about 0.01 Pa s to 2500 Pa s. The preferred molecular weight of the crosslinkable polysiloxane often depends upon the desired viscosity of the RTV silicone composition prior to crosslinking. In general, as the molecular weight is increased, the viscosity of the uncrosslinked composition correspondingly increases.

In one embodiment, a crosslinkable polysiloxane is represented by Formula I:



wherein R¹ and R² are independently organofunctional groups and n is from about 10 to about 6,000.

The groups R¹ and R² of Formula I represent the "terminal" portions of the polymer chain and are often the sites for the attachment of one or more functional groups, i.e., the groups which participate in the crosslinking reaction. In one embodiment, one or more sites depicted in Formula I as having methyl groups instead contain the one or more organofunctional groups. Likewise, R¹ and/or R² may not be the site of the one or more organofunctional groups. Therefore,

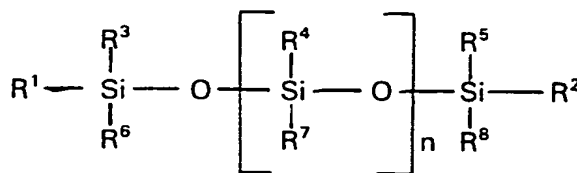
Formula I is intended to merely represent a "typical" crosslinkable polysiloxane with terminal functional groups. The site of attachment of the functional groups is not presently believed to be particularly important. In one embodiment, the average value of n is from about 25 to about 5,000. In another embodiment, the average value of n is from about 50 to about 2,500. In yet another embodiment, the average value of n is from about 100 to about 1,000. Mixtures of more than one molecular weight may likewise be utilized.

The one or more organofunctional groups preferably possess an unsaturated carbon carbon bond, such as an unsaturated aliphatic group. In one embodiment, each organofunctional group independently is a hydrocarbyl group containing from 1 to about 20 carbon atoms, and preferably from about 2 to about 10 carbon atoms. Examples of organofunctional groups include alkenyl, cycloalkenyl, such as vinyl, allyl, 1-hexenyl and cyclohexenyl. A preferred organofunctional group is a vinyl group.

When certain properties are desired, other monovalent hydrocarbyl and halogenated monovalent hydrocarbyl groups (e.g., alkyls, phenyl, cyanoethyl, and trifluoropropyl) can be substituted for the methyl groups of Formula I.

The term "hydrocarbyl" as used herein includes hydrocarbon as well as substantially hydrocarbon groups. Substantially hydrocarbon describes groups which contain heteroatom substituents which do not alter the predominantly hydrocarbon nature of the group. Examples of hydrocarbyl groups include hydrocarbon substituents, i.e., aliphatic (e.g., alkyl or alkenyl) and substituted aliphatic substituents, alicyclic (e.g., cycloalkyl, cycloalkenyl) substituents, aromatic-, aliphatic- and alicyclic-substituted aromatic substituents. Heteroatoms include, by way of example, halogens including fluorine and chlorine, nitrogen, oxygen and sulfur. In one embodiment, the crosslinkable polysiloxane is a diorgano polysiloxane.

Accordingly, in another embodiment, the crosslinkable polysiloxane is represented by Formula II:



Formula II

5 wherein R^1 and R^2 are independently hydrogen, hydroxyl, and organofunctional groups, R^3 , R^4 , R^5 , R^6 , R^7 , and R^8 are independently hydrogen, and hydrocarbyl groups containing from 1 to about 20 carbon atoms and n is from about 10 to about 6,000. For example, R^1 , R^2 , R^3 , R^4 , R^5 , R^6 , R^7 , and R^8 are radicals independently selected from hydrogen, hydroxyl, aryl and halogenated aryl such as phenol, methylphenol, chlorophenol, naphthyl, alkyl such as methyl ethyl, etc.;
 10 aliphatic and cycloaliphatic such as methyl, ethyl, propyl, cyclohexyl, cyclobutyl, etc., alkenyl such as vinyl, allyl, etc.; and cyanoalkyl such as cyanoethyl, cyanopropyl, cyanobutyl.

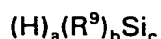
Examples of the crosslinkable polysiloxane include dimethyl polysiloxane,
 15 dimethyl diphenyl polysiloxane, and trifluoropropyl methyl polysiloxane blocked with an appropriate end group, such as a vinyl group.

The preferred amount of the crosslinkable polysiloxane component varies depending upon the desired physical properties of the RTV silicone composition (such as the desired uncured viscosity, cured hardness, etc.). In part due to the
 20 wide range of acceptable molecular weights for the crosslinkable polysiloxane component and the many types of adjuvants which may be added to the RTV silicone composition this amount varies widely. In one embodiment, the amount of the crosslinkable polysiloxane in the RTV silicone composition is from about 10% to about 99% by weight. In another embodiment, the amount of the crosslinkable polysiloxane in the RTV silicone composition is from about 20% to about 90% by
 25 weight. In yet another embodiment, the amount of the crosslinkable polysiloxane in the RTV silicone composition is from about 25% to about 80% by weight.

The crosslinking agent contains at least one silicon-hydrogen linkage and can be a polymeric compound or a compound that is not polymeric. These compounds
 30 are known in the art and are disclosed, for example, in U.S. Patents 3,159,662; 3,220,972; and 3,410,886; which are hereby incorporated by reference in this regard. The crosslinker containing the silicon-hydrogen linkage preferably contains

at least about two silicon-hydrogen linkages per molecule, with preferably no more than about three hydrogen atoms attached to any one silicon atom. For example, in one embodiment, the crosslinking agent is an organohydrogenpolysiloxane.

In one embodiment, compounds having a silicon-bonded hydrogen atom which can be used as the crosslinking agent in the present invention are organohydrogensilanes having empirical Formula III:

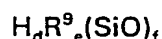


Formula III

wherein each R^9 can be the same or different and represents an organic group, preferably selected from the group consisting of monovalent hydrocarbyl groups, monovalent hydroalkoxyl groups and halogenated monovalent hydrocarbyl groups, any of which containing from 1 to about 20 carbon atoms, c is from 1 to about 10,000, a is at least about 2 and less than or equal to c when c is greater than 1, and the sum of a and b equals the sum of 2 and two times c.

In another embodiment, compounds having a silicon-bonded hydrogen atom which can be used as the crosslinking agent in the present invention are organohydrogencyclopolsiloxanes having empirical Formula IV:

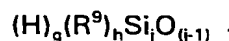
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Formula IV

wherein R^9 is as defined above, f is from about 3 to about 18, d is at least about 2 and less than or equal to f, and the sum of d and e equals two times f.

In another embodiment, compounds having a silicon-bonded hydrogen atom which can be used as the crosslinking agent in the present invention are organohydrogenpolysiloxane polymers or copolymers having empirical Formula V:

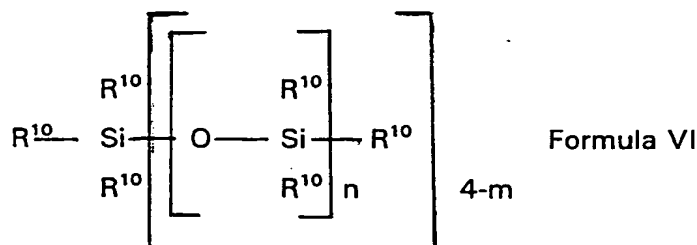


Formula V

wherein R^9 is as defined above, j is from about 2 to about 10,000, g is at least about 2 and less than or equal to j, and the sum of g and h equals the sum of about 2 and two times j.

Specific groups represented by R^9 include, for example, alkyl groups having from 1 to about 18 carbon atoms, such as methyl, ethyl, propyl, octyl, and octadecyl groups, cycloalkyl groups having from about 5 to about 7 ring carbon atoms, such as cyclohexyl and cycloheptyl groups, aryl groups having from about 6 to about 18 carbon atoms, such as phenyl, naphthyl, tolyl, xylyl groups, alkoxy groups having from 0 to about 18 carbon atoms, such as hydroxyl, methoxyl, ethoxyl, propoxyl, and combinations of alkyl and aryl groups, such as aralkyl groups, such as, benzyl and phenylethyl, and halo-substituted groups thereof, such as chloromethyl, chlorophenyl, and dibromophenyl groups. In one embodiment, the R^9 group is methyl or both methyl and phenyl. In another embodiment, the R^9 group is an unsaturated aliphatic group having from 1 to about 20 carbon atoms, such as alkenyl and cycloalkenyl groups, including vinyl, allyl and cyclohexenyl groups. When the R^9 group is a group with aliphatic unsaturation, the silicon compound containing silicon-hydrogen linkages can be reacted with itself to form a polymer.

In one embodiment, the compound having silicon-bonded hydrogen useful as the crosslinking agent in the present invention is a polyorganohydrogenpolysiloxane having general Formula VI



wherein each R¹⁰ is independently hydrogen or hydrocarbyl containing from 1 to about 20 carbon atoms. In another embodiment, each R¹⁰ is independently hydrogen, an alkyl group containing from 1 to about 18 carbon atoms, a cycloalkyl group containing from about 3 to about 12 carbon atoms, or a phenyl group (substituted or unsubstituted), at least about two but not more than about one-half of all the R¹⁰ groups in the siloxane are hydrogen, m is 0,1,2, or 3, and n has an average value from 1 to about 10,000.

The amount of the crosslinking agent component varies to provide the desired degree of crosslinking of the RTV silicone composition. In part, due to the

wide range of acceptable molecular weights for the crosslinkable polysiloxane, this amount can be adequately described in terms of the ratio of Si—H groups to organofunctional groups in the RTV silicone composition. In one embodiment, the ratio of Si—H groups to organofunctional groups is from about 0.2:1 to about 20:1. In another embodiment, the ratio is from about 1:1 to about 10:1. In yet another embodiment, the ratio is from about 1.5:1 to about 4:1.

Alternatively, the amount of the crosslinking agent in the RTV silicone composition can be adequately described in terms of parts by weight of the crosslinkable polysiloxane. In one embodiment, the RTV silicone composition contains from about 0.01 to about 50 parts by weight of the crosslinking agent per 100 parts by weight of the crosslinkable polysiloxane. In another embodiment, the RTV silicone composition contains from about 0.1 to about 25 parts by weight of the crosslinking agent per 100 parts by weight of the crosslinkable polysiloxane. In yet another embodiment, the RTV silicone composition contains from about 1 to about 10 parts by weight of the crosslinking agent per 100 parts by weight of the crosslinkable polysiloxane. The RTV silicone composition contains a catalyst, which is typically a metal catalyst, typically a transition metal catalyst, and even more typically a platinum catalyst. The crosslinkable polysiloxane and the crosslinking agent react in the presence of the catalyst. Other catalysts include peroxide catalysts, oxime catalysts, acetoxy catalysts, hydroxyl catalysts, aziridine catalysts, iron catalysts, tin catalysts, titanium catalysts, palladium catalysts, and the like.

In one embodiment, the RTV silicone composition contains from about 1 to about 500 parts per million (ppm) of a metal catalyst such as platinum. In another embodiment, the RTV silicone composition contains from about 10 to about 250 ppm of a metal catalyst such as platinum. In yet another embodiment, the RTV silicone composition contains from about 25 to about 200 ppm of a metal catalyst such as platinum. The catalyst can be a solid metal catalyst deposited on gamma-alumina or charcoal or it can be a solubilized metal complex such as platinum complex. The solubilized metal complexes are preferred since they tend to be more reactive. Solubilized platinum complexes include those having the formula, $(\text{PtCl}_2 \cdot \text{Olefin})_2$ and $\text{H}(\text{PtCl}_3 \cdot \text{Olefin})$ as described in U.S. Patent 3,159,601, which

is hereby incorporated by reference in this regard. The olefin shown in the previous two chemical formulae can be almost any type of olefin, but is preferably an alkenylene having from about 2 to about 8 carbon atoms, a cyclo alkenylene having from about 5 to about 7 carbon atoms or styrene. Specific olefins utilized in the above formulae are ethylene, propylene, the various isomers of butylene octylene, cyclopentene, cyclohexene, cycloheptene, etc. For example, such platinum catalysts include $[(CH_2CH_2).PtCl_2]_2$; $(PtCl_2.C_3H_6)_2$, etc. A further platinum containing material suitable for use in the RTV silicone composition is a platinum chloride cyclopropane complex $(PtCl_2 \cdot C_3H_6)_2$ described in U.S. Patent 3,159,662, which is hereby incorporated by reference in this regard. For example, such platinum catalysts include the reaction product of chloroplatinic acid hexahydrate and octyl alcohol, etc.

In another embodiment, the platinum containing material can be a complex formed from chloroplatinic acid with up to about two moles per gram of platinum of at least one of an alcohol, ether, aldehyde as described in U.S. Patent 3,220,972, which is hereby incorporated by reference in this regard. In another embodiment, the catalyst is that disclosed U.S. Patent 3,419,513, which is hereby incorporated by reference in this regard.

In yet another embodiment, the platinum catalyst employed is disclosed in U.S. Patent 3,775,452, which is hereby incorporated by reference in this regard. Generally speaking, this type of platinum complex is formed by reacting chloroplatinic acid containing about 4 moles of water of hydration with tetravinylcyclotetrasiloxanes in the presence of sodium bicarbonate in an ethanol solution. The Karstedt platinum catalyst is typically a solubilized platinum complex of platinum with a linear or cyclic low molecular weight vinyl terminated polysiloxane polymer. In still yet another embodiment, the catalyst employed is disclosed in U.S. Patent 3,516,946, which is hereby incorporated by reference in this regard, which comprises a complex formed between platinum and a vinyl-containing cyclopolysiloxane such as methyl, vinyl cyclotetrasiloxane.

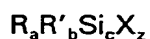
In one embodiment, the catalyst is a solubilized platinum complex produced by complexing platinum with tetravinyl dimethyldisiloxane which is a Karstedt

catalyst. The reaction is carried out by mixing the silanol containing polymer with the hydride and the solubilized platinum complex as disclosed above.

In another embodiment, the Karstedt platinum catalysts are described in at least one of U.S. Patents 3,715,334; 3,775,452 and 3,814,730 which are hereby incorporated by reference in this regard. To produce a Karstedt catalyst according to this embodiment, utilized are a platinum halide and a complexing material in the form of an unsaturated organosilicon material containing at least one of the three:

(1) unsaturated silanes having empirical Formula VII:

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Formula VII

wherein each R is independently free of aliphatic unsaturation and is a monovalent hydrocarbon radicals, each R' is independently a monovalent aliphatically unsaturated hydrocarbon radical, each X is independently a hydrolyzable radical, c is from 1 to about 10,000, b is greater than about 2 and the sum of a, b and z equals the sum of 2 and two times c for a linear or branched silane and wherein c is from about 4 to about 18 and the sum of a, b and z equals two times c for a cyclic silane;

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(2) unsaturated linear or branched siloxanes of Formula VIII:

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Formula VIII

wherein R and R' are as defined above, f is from about 2 to about 10,000, e is greater than about 2 and the sum of d and e equals the sum of 2 and two times f; and

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(3) unsaturated cyclic siloxanes of Formula IX



Formula IX

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wherein R and R' are as defined above, f is from about 3 to about 18, and the sum of d and e equals two times f.

In this embodiment, the Karstedt catalyst is made by effecting contact between an unsaturated organosilicon material as defined by at least one of Formulae VII, VIII and IX above, and a platinum compound, such as a platinum halide, to provide for the production of a mixture sometimes having a concentration of inorganic halogen; if present, treating the resulting mixture to effect the removal of inorganic halogen; and recovering therefrom a platinum-siloxane complex. In a preferred embodiment, the recovered platinum-siloxane complex has less than about 0.1 gram atoms of halogen, per gram atom of platinum, and more preferably is substantially halogen free.

In this embodiment, examples of R radicals include alkyl radicals such as methyl, ethyl, propyl, butyl, hexyl, heptyl, octyl, etc.; cycloalkyl radicals such as cyclohexyl, cycloheptyl, etc.; aryl radicals such as phenyl, methyl, tolyl, xylyl, etc.; aralkyl radicals such as benzyl, phenylethyl, phenylpropyl, etc. Also in this embodiment, examples of R' radicals include aliphatically unsaturated radicals such as ethynyl, 1-propynyl, etc.; vinyl, allyl, and cycloalkenyl radicals, such as cyclopentenyl, cyclohexenyl, cycloheptenyl, cyclooctenyl, etc.

It is desirable that neither the R nor the R' radicals have chemically combined halogen since the presence of such halogen attached to the hydrocarbon group in the platinum complex in some instances acts to inhibit the catalysis effected by the complex. Accordingly, it is preferred to catalyze silanes and siloxanes of Formulae VII, VIII and IX in forming the platinum catalyst of the present invention that do not have combined halogen.

Examples of unsaturated silanes described by Formula VII include tetravinylsilane, tri-allylmethylsilane, divinyl dimethylsilane, tri-vinylphenylsilane, divinylmethylphenylsilane, divinylmethylethoxysilane, divinylmethylacetoxysilane, etc. Examples of unsaturated siloxanes described by Formula VIII include disiloxanes of Formula X:

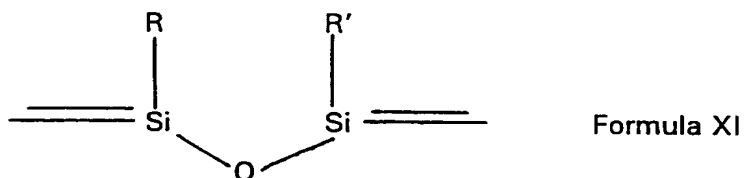


Formula X

wherein R, R', are as defined above, h has a value per silicon atom of at least one and the sum of g and h, per silicon atom, is equal to about 3. Examples of

disiloxanes described by Formula X include symdivinyltetramethyldisiloxane, 1,3-divinyltetramethyldisiloxane, hexavinyldisiloxane, 1,1,3-trivinyltriethyldisiloxane, symtetravinyl dimethyldisiloxane, etc. Examples of unsaturated siloxanes described by Formula IX include cyclopolysiloxanes such as 1,3,5-trivinyl-1,3,5-trimethylcyclotrisiloxane, and 1,3,5,7-tetraallyl-1,3,5,7-tetraphenylcyclotetrasiloxane 1,3-divinyloctamethylcyclopentasiloxane, etc.

In another embodiment, the platinum-siloxane complexes of platinum and organosiloxanes of Formulae VIII and IX are made utilizing a platinum halide, and an unsaturated linear, branched or cyclic siloxane of Formula VIII or IX having at least one structural unit of Formula XI



wherein the unsatisfied valences of the above structural unit can be satisfied by R, R' and oxygen radicals and where R and R' are as previously defined.

The platinum compounds which can be employed in making the catalysts include $\text{H}_2\text{PtCl}_6 \cdot n\text{H}_2\text{O}$ and metal salts such as $\text{NaHPtCl}_6 \cdot n\text{H}_2\text{O}$, $\text{KHPtCl}_6 \cdot n\text{H}_2\text{O}$, $\text{Na}_2\text{PtCl}_6 \cdot n\text{H}_2\text{O}$, $\text{K}_2\text{PtCl}_6 \cdot n\text{H}_2\text{O}$, $\text{PtCl}_4 \cdot n\text{H}_2\text{O}$ and platinous type halides such as PtCl_2 , $\text{Na}_2\text{PtCl}_4 \cdot n\text{H}_2\text{O}$, $\text{H}_2\text{PtCl}_4 \cdot n\text{H}_2\text{O}$, $\text{NaHPtCl}_4 \cdot n\text{H}_2\text{O}$, $\text{KHPtCl}_4 \cdot n\text{H}_2\text{O}$, and K_2PtBr_4 .

The amount of the platinum complex component is sufficient to provide the desired degree of crosslinking of the RTV silicone composition within a reasonable time, such as within about 2 hours. In a preferred embodiment, the desired degree of crosslinking of the RTV silicone composition within about 1 hour. In part, due to the wide range of acceptable molecular weights for the crosslinkable polysiloxane, the amount can in one sense be suitably described in terms of the ratio of Pt atoms to organofunctional groups in the RTV silicone composition. In one embodiment, the ratio of Pt atoms to organofunctional groups is from about 1:2 to about 1:500. In another embodiment, the ratio of Pt atoms to organofunctional groups is from about 1:10 to about 1:200. In yet another

embodiment, the ratio of Pt atoms to organofunctional groups is from about 1:30 to about 1:70.

The RTV silicone composition may optionally contain one or more additives. Additives include fillers, medicaments, stabilizers, thickeners, pigments, dyes and antioxidants. In one embodiment, the RTV silicone composition contains from about 0.001% to about 35% by weight of at least one additive. In another embodiment, the RTV silicone composition contains from about 0.01% to about 30% by weight of at least one additive. In another embodiment, the RTV silicone composition contains from about 0.1% to about 25% by weight of at least one additive.

Examples of fillers include fumed silica, quartz powder, glass fibers, carbon, metal oxides such as iron oxide, titanium oxide, and cerium oxide, and metal carbonates such as calcium carbonate and magnesium carbonate. Fumed silica is preferred since it can maintain cured RTV silicone compositions transparent.

Fumed silicas are available from Degussa under the trade designation Aerosil®.

Stabilizers specifically include amine stabilizers. Suitable thickeners are the swelling agents customarily used for gel formation in galenic pharmacy. Examples of suitable thickeners include natural organic thickeners, such as agar-agar, gelatin, gum arabic, a pectin, etc., modified organic natural compounds, such as carboxymethylcellulose or cellulose ethers, or fully synthetic organic thickeners, such as polyacrylic compounds, vinyl polymers, or polyethers.

Medicaments include analgesic-antirheumatic agents and antibiotics. Analgesic-antirheumatic agents include phenylbutazone, oxyphenbutazone, indomethacin, naproxen, ibuprofen, acetaminophen, acetylsalicylic acid, etc.

Antibiotics include various penicillins, tetracyclines, streptomycins, etc.

Examples of RTV silicone compositions that are commercially available include silicon RTVs from Nusil Technology, including those under the trade/product designations CF15-2186, CF19-2186, MED1-4013, and MED2-4013; and RTV silicone solutions from Factor II, Inc./Dow Corning, including those under the trade/product designations MDX4-4159, A-2186, and A-588. Preferred RTV silicone compositions are the MED1-4013 and CF19-2186 available from Nusil Technology. Various other RTV silicone compositions, crosslinkable polysiloxanes,

crosslinking agents, catalysts and additives are available from Silicones, Inc., Precision Silicones, Inc., the Walco Materials Group of Synair Corp., General Electric, Bayer, Huls America, Shiastu, Shin Etsu, Rhone Poulenc, Wacker Silicones, Degussa, Dow Corning, and Cabot Corp.

5 Just prior to applying the RTV silicone composition to a wound, all of the components are mixed. In a preferred embodiment, the RTV silicone composition is made from a two part RTV silicone composition wherein one part contains the crosslinking agent and the crosslinkable polysiloxane while a second part contains the catalyst and the crosslinkable polysiloxane. One or both parts optionally
10 contain additives. Once all of the components are mixed, the composition begins to cure (crosslinking is commenced).

In a preferred embodiment, a first part has a viscosity from about 60,000 to about 120,000 cps while the second part has a viscosity from about 40,000 to about 100,000 cps. In another preferred embodiment, a first part has a viscosity
15 from about 70,000 to about 100,000 cps while the second part has a viscosity from about 50,000 to about 90,000 cps.

The work time of the mixed RTV silicone composition is from about 2 minutes to about 15 minutes. In a preferred embodiment, the work time of the mixed RTV silicone composition is from about 3 minutes to about 12 minutes. The
20 work time is the amount of time the mixed RTV silicone composition is a substantially flowable state. As such, the RTV silicone composition is easily applied to a wound. After application, the RTV silicone composition is smoothed to a desired thickness. The mixed RTV silicone composition is substantially tack-free about 30 minutes after mixing. In a preferred embodiment, the mixed RTV
25 silicone composition is substantially tack-free about 30 minutes after mixing. After about 45 minutes after all of the components are mixed, it is difficult to apply the RTV silicone composition to a wound.

In a preferred embodiment, a release agent is applied to objects used to
30 apply the RTV silicone composition to a wound. For example, if applied by hand, a release agent is applied to the rubber gloves cover an applicators hands to minimize the amount of RTV silicone composition that may adhere to the gloves.

It is difficult to identify a precise time when curing is completed. When the composition has substantially cured, a flexible membrane is formed. Typically, the RTV silicone composition is substantially cured at least about 3 hours after application to a wound. In another embodiment, the RTV silicone composition is substantially cured at least about 6 hours after application to a wound. In yet another embodiment, the RTV silicone composition is substantially cured at least about 12 hours after application to a wound. The RTV silicone composition may take 1 or 2 days to fully cure, but substantial curing is adequate for the purposes of this invention.

In a preferred embodiment, no padding is applied to the wound in addition to the RTV silicone composition. In this connection, it is not necessary to apply a textile or plastic support strip with the RTV silicone composition.

The thickness of the RTV silicone composition is sufficient to act as barrier to infection causing species as well as sufficient to retain moisture in the wound. In one embodiment, the thickness of the RTV silicone composition applied to the wound is from about 0.1 mm to about 5 mm. In another embodiment, the thickness of the RTV silicone composition applied to the wound is from about 0.25 mm to about 3 mm. In another embodiment, the thickness of the RTV silicone composition applied to the wound is from about 0.5 mm to about 2 mm.

The RTV silicone composition may be custom fit to any contoured or shaped surface. This is an advantage over and in contrast with prefabricated bandaids or dressings, or dressings that must be cut and fit to a wound.

In one embodiment, the RTV silicone composition is transparent or substantially transparent. The development of a transparent membrane permits visual observation and monitoring of the wound as it heals. The transparent membrane also provides a relatively inconspicuous dressing for the wound.

The RTV silicone composition forms a membrane that is continuous or substantially continuous. The continuous nature of the membrane contributes to the ability of the membrane to retain moisture in the wound. The continuous nature of the membrane contributes to the ability of the membrane to act as a bacterial barrier. In one embodiment, the RTV silicone membrane is free or at least substantially free of air bubbles.

Any wound may be treated in accordance with the present invention. Such wounds include cuts, abrasions traditional surgical wounds (such as those resulting from the use of a scalpel) and laser surgery wounds. In a preferred embodiment of the present invention, the wound treated is a laser surgery wound. Laser surgery wounds are caused by any suitable medical laser including carbon dioxide lasers, YAG lasers, erbium YAG lasers, ruby lasers, Alexandrite lasers, Q-switched Alexandrite lasers, Q-switched neodymium YAG lasers, frequency doubled neodymium YAG lasers, copper vapor lasers, argon lasers, and pulsed dye lasers.

The RTV silicone composition membrane remains on the wound for a time sufficient to permit healing of the wound. In one embodiment, the RTV silicone composition forming a membrane remains on the wound at least about 1 day. In another embodiment, the RTV silicone composition forming a membrane remains on the wound at least about 2 days. In yet another embodiment, the RTV silicone composition forming a membrane remains on the wound at least about 4 days. In still yet another embodiment, the RTV silicone composition forming a membrane remains on the wound at least about 6 days. In a preferred embodiment, the RTV silicone composition forming a membrane remains on the wound from about 7 days to about 10 days. Although not typically necessary, on wounds in extremely mobile areas of the body, it may be required to change the silicone composition dressing every 1, 2 or 3 days.

After the RTV silicone composition has been on a wound for at least about 1 day, and healing is promoted and/or substantially completed, the RTV silicone membrane is removed by gently peeling it from the wound. The healed wound is characterized by decreased redness, moistness, minimal scarring. The healed wound is generally in better condition than similar wounds covered with conventional dressings. Especially with wounds caused by laser surgery, the healed laser surgery wound is generally in better condition than similar wounds covered with conventional dressings.

While the invention has been explained in relation to its preferred embodiments, it is to be understood that various modifications thereof will become apparent to those skilled in the art upon reading the specification. Therefore, it is

to be understood that the invention disclosed herein is intended to cover such modifications as fall within the scope of the appended claims.

Claims

What is claimed is:

1. A method of treating a wound, comprising:
applying to the wound a room temperature vulcanizing silicone composition comprising a crosslinkable polymer, a crosslinking agent, and a catalyst;
5 permitting the room temperature vulcanizing silicon composition to cure thereby forming a membrane having a thickness from about 0.1 mm to about 5 mm; and
removing the membrane from the wound after at least about 1 day.
2. The method of claim 1, wherein the room temperature
10 vulcanizing silicone composition is a platinum catalyzed silicone elastomer.
3. The method of claim 1, wherein the crosslinkable polymer comprises a polysiloxane having one or more functional groups, the functional groups comprising at least one of vinyl, allyl, 1-hexenyl and cyclohexenyl groups.
4. The method of claim 1, wherein the crosslinking agent
15 comprises an organohydrogenpolysiloxane containing at least one silicon-hydrogen linkage.
5. The method of claim 1, wherein the catalyst comprises a solubilized platinum complex.
6. The method of claim 1, wherein the room temperature
20 vulcanizing silicon composition further comprises fumed silica.
7. The method of claim 1, wherein the membrane has a thickness from about 0.5 mm to about 2 mm.
8. A method of treating a laser surgery wound, comprising:
combining a first composition comprising a first crosslinkable polymer
25 and a crosslinking agent with a second composition comprising a second crosslinkable polymer and a platinum catalyst to form a room temperature vulcanizing silicon composition comprising the first and second crosslinkable polymers, the crosslinking agent, and the platinum catalyst;
applying to the laser surgery wound the room temperature vulcanizing
30 silicon composition;

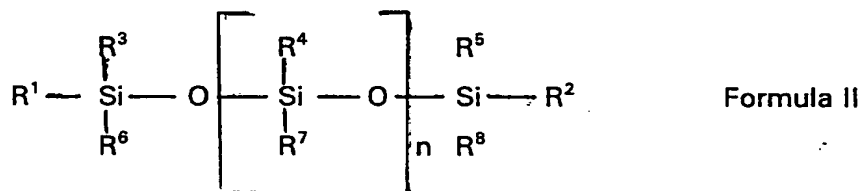
permitting the room temperature vulcanizing silicon composition to cure thereby forming a substantially transparent membrane having a thickness from about 0.25 mm to about 3 mm; and

removing the substantially transparent membrane from the laser surgery wound after at least about 2 days.

9. The method of claim 8, wherein the room temperature vulcanizing silicon composition comprises from about 10% to about 99% by weight of the first and second crosslinkable polymers, from about 0.01 to about 50 parts by weight of the crosslinking agent per 100 parts by weight of the first and second crosslinkable polysiloxanes, and from about 1 to about 500 parts per million of the platinum catalyst.

10. The method of claim 8, wherein the first and second crosslinkable polymers comprise the same crosslinkable polymer.

11. The method of claim 8, wherein at least one of the first crosslinkable polymer and the second crosslinkable polymer comprise a compound represented by Formula II:



wherein R¹ and R² are independently hydrogen, hydroxyl, and organofunctional groups, R³, R⁴, R⁵, R⁶, R⁷, and R⁸ are independently hydrogen, and hydrocarbyl groups containing from 1 to about 20 carbon atoms and n is from about 10 to about 6,000.

12. The method of claim 8, wherein the crosslinking agent comprises an organohydrogenpolysiloxane containing at least about two silicon-hydrogen linkage.

13. The method of claim 8, wherein at least one of the first composition and second composition, and the room temperature vulcanizing silicon composition further comprises at least one of fillers, medicaments, stabilizers, thickeners, pigments, dyes and antioxidants.

14. The method of claim 8, wherein the substantially transparent membrane is removed from the laser surgery wound after at least about 4 days.

15. A method of treating a laser surgery wound, comprising:
combining a first composition comprising a first crosslinkable polymer
5 and a crosslinking agent with a second composition comprising a second
crosslinkable polymer and a platinum catalyst to form a room temperature
vulcanizing silicon composition comprising the first and second crosslinkable
polymers, the crosslinking agent, and the platinum catalyst;

10 applying to the laser surgery wound the room temperature vulcanizing
silicon composition;

permitting the room temperature vulcanizing silicon composition to
cure thereby forming a substantially transparent membrane having a thickness from
about 0.25 mm to about 3 mm; and

15 removing the substantially transparent membrane from the laser
surgery wound after at least about 4 days.

16. The method of claim 15, wherein the laser surgery wound is
caused by one of carbon dioxide lasers, YAG lasers, erbium YAG lasers, ruby
lasers, Alexandrite lasers, Q-switched Alexandrite lasers, Q-switched neodymium
20 YAG lasers, frequency doubled neodymium YAG lasers, copper vapor lasers, argon
lasers, and pulsed dye lasers.

17. The method of claim 15, wherein the room temperature
vulcanizing silicon composition is applied to the laser surgery wound within about
45 minutes of combining the first composition with the second composition.

25 18. The method of claim 15, wherein the room temperature
vulcanizing silicon composition comprises from about 20% to about 90% by
weight of the first and second crosslinkable polymers, from about 0.1 to about 25
parts by weight of the crosslinking agent per 100 parts by weight of the first and
second crosslinkable polysiloxanes, and from about 10 to about 250 parts per
30 million of the platinum catalyst.

19. The method of claim 15, wherein at least one of the first
composition and second composition, and the room temperature

vulcanizing silicon composition further comprises at least one of fillers, medicaments, stabilizers, thickeners, pigments, dyes and antioxidants.

20. The method of claim 15, wherein at least one of the first composition and second composition, and the room temperature

5 vulcanizing silicon composition further comprises fumed silica.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/40029**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) : A61L 15/22; A61K 9/70; CO8G 77/06, 77/08

US CL : Please See Extra Sheet.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/dig.21; 424/443, 445; 427/2.31, 155; 524/860, 861, 862, 863; 525/478; 528/15, 31, 32, 33, 34, 37, 901; 602/52, 904; 604/304

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Extra Sheet.**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,791,149 A [POCKNELL] 13 December 1988, col. 3, lines 42-53, col. 4, lines 5-68, col. 5, lines 3-7, col. 5, lines 20-43, col. 5, lines 63-66, col. 6, lines 1-14, col. 6, lines 59-68, col. 7, lines 1-3, col. 7, lines 16-46.	1-7
Y		8-20
Y	US 4,638,800 A [MICHEL] 27 January 1987, col. 2, lines 18-21.	8-20
A	US 4,987,893 A [SALAMONE et al.] 29 January 1991.	
A	US 5,010,115 A [GRISONI] 23 April 1991.	
A	US 5,103,812 A [SALAMONE et al.] 14 April 1992.	

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
22 AUGUST 2000Date of mailing of the international search report
06 SEP 2000Name and mailing address of the ISA/US
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/40029

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,153,231 A [BOUQUET et al.] 06 October 1992.	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/40029

A. CLASSIFICATION OF SUBJECT MATTER:

US CL :

128/dig.21; 424/443, 445; 427/2.31, 155; 524/860, 861, 862, 863; 525/478; 528/15, 31, 32, 33, 34, 37, 901; 602/52, 904; 604/304

B. FIELDS SEARCHED

Electronic data bases consulted (Name of data base and where practicable terms used):

APS search terms: polysiloxane, organopolysiloxane, polyorganosiloxane, polydiorganosiloxane, diorganopolysiloxane, silicone, wound, dressing, bandage, room temperature, curing, crosslinking, curable, crosslinkable, vulcanizing, vulcanizable, laser surgery, YAG, carbon dioxide